

Emerging Pathogens Workgroup's (EPWG) Mid-Year Update May 2022

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Agenda

- Background
- Membership/Organization/Affiliations
- Objectives of EPWG
- Charge Questions and Recommendations
- AD Management's Prioritization of Recommendations
- Next Steps: Current Deliverables/Ongoing Activities
- Question to PPDC

Emerging Viral Pathogens (EVP) Guidance

- In 2016, EPA finalized guidance for making claims against emerging viral pathogens that are not on EPA registered disinfectant labels:
 - <https://www.epa.gov/pesticide-registration/guidance-registrants-process-making-claims-against-emerging-viral-pathogens>
 - Followed a 30-day public comment period and included a response to comments

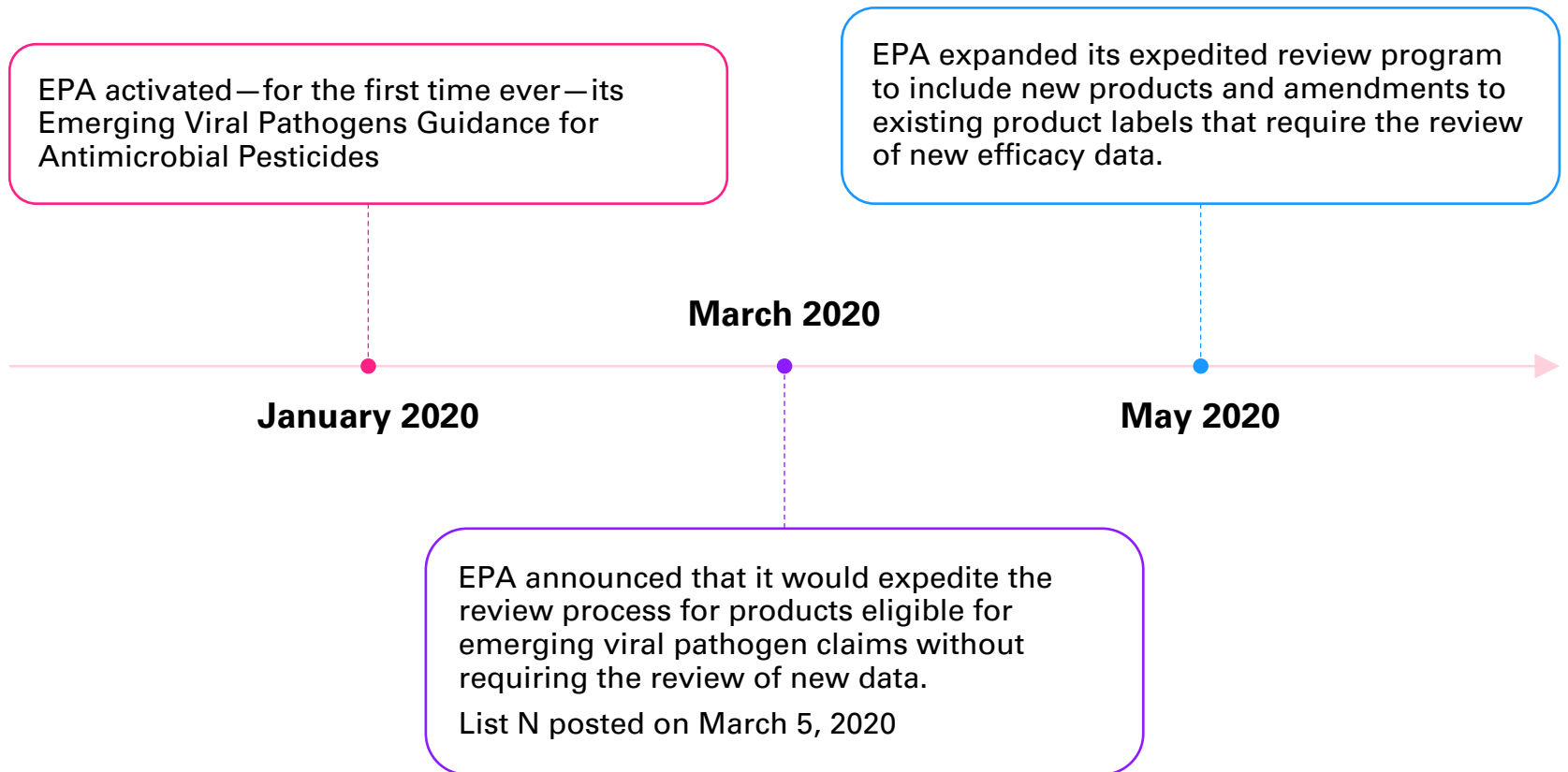
**GUIDANCE TO REGISTRANTS: PROCESS FOR MAKING
CLAIMS AGAINST EMERGING VIRAL PATHOGENS NOT ON
EPA-REGISTERED DISINFECTANT LABELS**

August 19, 2016

In this document:

- I. Background and Purpose
 - II. Viral Subgroup Classification
 - III. Product Eligibility Criteria
 - IV. Instructions for Using the Process
 - V. Outbreak Criteria Associated with Emerging Pathogens Process
 - VI. References
- Attachment 1 - Additional Terms of Registration
Attachment 2 - Process Example

EVP Activation and Events



EPA List N: Disinfectants for Use Against SARS-CoV-2

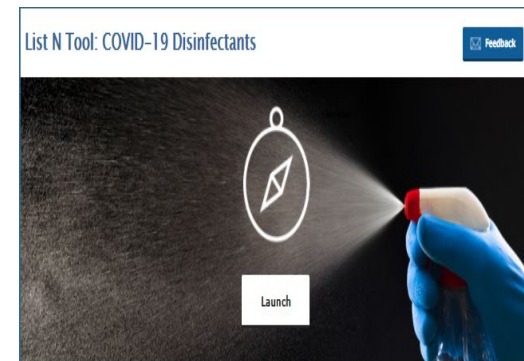
- On March 5, 2020, EPA posted List N: Disinfectants for Use Against SARS-CoV-2
 - Initial list contained ~90 products
- Significant improvements to the list have been made including:
 - the ability to search and sort a dynamic list
 - additional information helpful to end users (e.g., active ingredient, formulation type, use sites)
- Analytics

List N: Disinfectants for Coronavirus (COVID-19)

[Find a Product to Kill Coronavirus \(COVID-19\)](#)

[Infographic: How to use disinfectants safely and effectively - IMPORTANT, PLEASE READ](#)

[Use our advanced search option to find a product](#)



Emerging Pathogens Workgroup (EPWG) Origins

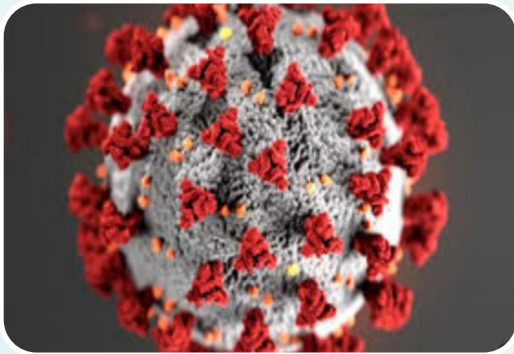
✓ **Conduct a retrospective of the COVID-19 crisis and the emerging viral pathogens policy to address:**

- ✓ Product availability
- ✓ Proper use of products/address misuses
- ✓ Bogus/misleading claims
- ✓ Any modifications to the EVP policy? Symbols?
- ✓ List N flexibility, pros/cons
- ✓ Other lists
- ✓ Other ways to address product selections
- ✓ Communications

EPWG Membership and Affiliations

Emerging Pathogens Workgroup (EPWG) Members	Organization (Affiliation)	
Matthew Arduino	Centers for Disease Control and Prevention	Federal
Ellen Baldassare	LANXESS Corporation	Registrant (Animal Health)
Steve Bennett	Household & Commercial Products Association	Trade Association
Elaine Black	Ecolab	Registrant and Disinfectant Formulator
Diane Boesenberg	Exponent	Technical Consultant
Milady Brutofsky	Lonza, LLC	Registrant
Emily Burke	American Chemistry Council, Center for Biocide Chemistries	Trade Association
Alexander Cook	First Group USA	User (Ground Transportation)
Patti Costello	American Hospital Association	User (Healthcare)
Lisa Dreilinger	Reckitt Benckiser	Registrant
Seth Goldberg	Steptoe & Johnson LLP	Regulatory and Legal Consultant
Joseph Grzywacz	Florida State University	Academia and User
Rhonda Jones	Scientific & Regulatory Consultants, Inc.	Regulatory and Technical Consultant
Pat Quinn	The Accord Group	Regulatory and Technical Consultant
Jamie Quon	The Clorox Company	Registrant and Disinfectant Formulator
Marylou Verder-Carlos	Exponent	Regulatory and Technical Consultant
Cheryl Woodward	Thor Specialties, Inc.	Registrant
Nancy Young	Airlines of America	User (Air Transportation)
Samantha Collins	US Environmental Protection Agency	Federal Regulatory
Komal Jain (Co-Chair)	American Chemistry Council, Center for Biocide Chemistries	Trade Association
Tajah Blackburn (Co-Chair)	US Environmental Protection Agency	Federal Regulatory

EPWG Objectives



Objective #1:

Assess EPA's COVID-19 response and stakeholder experiences with the Emerging Viral Pathogens (EVP) Guidance for Antimicrobial Pesticides

Objective #2:

Assess the user experience with antimicrobial disinfection products registered by the EPA for infection control

Objective #3:

Provide recommendations to EPA for policy improvements and identify educational gaps

Summary of Recommendations

Charge Question	Number of Recommendations
CQ#1: What are the strengths and weaknesses of the first use of the Emerging Viral Pathogens (EVP) Guidance during the COVID-19 Pandemic?	17 recommendations
CQ#2: What flexibilities are needed (not provided) by guidance, regulations, etc., to address issues faced in a pandemic or other emergency?	17 recommendations
CQ#3: What education is needed during a pandemic or other emergency for the public, end users, and other regulating authorities?	48 recommendations spanning over 4 pages
CQ#4: How can EPA's enforcement program be strengthened to expeditiously respond to fraudulent/misbranded products in the marketplace during a pandemic or other emergency?	4 recommendations

AD's Prioritization Buckets



Highest Importance/ Priority



Medium Priority



Needs Process Development


- Recommendations require additional work by a follow-up group; therefore, no EPA priority has been set at this time.



Long-term Issues (Parking Lot Issues)

- Recommendations that EPA will not be able to address in the short term and will necessitate significant resources to implement; therefore, no EPA prioritization is currently provided

Highest Importance/Priority— Overarching Topics

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- Improved Communication and Transparency
 - Formation of New Workgroup
 - Efficacy Guidance
 - Education
 - Collaboration
 - Product Verification

Improved Communication and Transparency

Recommendation	Deliverable	Recommendation Location
<ul style="list-style-type: none"> Revise EVP to instruct EPA to issue explicit statement when EVP is triggered, extended, and halted Establish/maintain EPA webpage that addresses pandemics, increases transparency, and communicates early/often for leveled playing field Addresses how variants will be handled 	<p>Landing Page</p> <ul style="list-style-type: none"> Initiated 11/2021 <p>Currently captures</p> <ul style="list-style-type: none"> ✓ Variants ✓ Trigger 	<p>CQ#1: Issue #1 CQ#2: Issue #1</p>
<ul style="list-style-type: none"> Details for pathogen specific testing guidance 	<ul style="list-style-type: none"> ✓ Pathogen specific guidance will be housed on the EVP landing page 	<p>CQ#2: Issue #2</p>
<ul style="list-style-type: none"> Refine procedures for establishing, expanding, and pruning lists EPA established webpage to address pandemics with hyperlinks to requisite documents Provide documents in both English and Spanish, at a minimum Provide information on effective products 	<ul style="list-style-type: none"> ✓ Refine the “List”; to date some revision have taken place (Lists M, O and P) and add hyperlinks ✓ Will add pandemic web content including helpful links section ✓ Lists will be renamed with pathogen designation 1st, then letter designation ✓ Lists M -P are searchable with FAQ’s ✓ Page and FAQs in Spanish 	<p>CQ#1, Issue #1 CQ#2, Issue #1 CQ#3, Issue #1</p>
<ul style="list-style-type: none"> Correct misinformation 	<ul style="list-style-type: none"> ✓ Ongoing; Case-by-case (e.g., S18 revocation, List N corrections, revisions to FAQs) 	<p>CQ#3, Issue #1</p>

Formation of New Workgroup

Recommendation	Deliverable	Recommendation Location
<ul style="list-style-type: none">Formation of additional workgroups consisting of a subset of individuals from the EPWG (and maybe others) to further develop the icons through the finalization	✓ Develop additional workgroups to address charge questions 1-4,	CQ#1, Issue #2

Efficacy Guidance

Recommendation	Deliverable	Recommendation Location
<ul style="list-style-type: none"> Incorporate ESS testing guidance into the 810 Guidelines and extended to additional use sites/strains 	<ul style="list-style-type: none"> ✓ ESS guidance will be incorporated into 810 Guidelines; ✓ Consideration for additional use sites/strains is ongoing 	CQ#2, Issue #2
<ul style="list-style-type: none"> Incorporate residual guidance into the 810 Guidelines and extended to additional use sites/strains 	<ul style="list-style-type: none"> ✓ Residual guidance is being revised (completion date: end of FY21); ✓ Incorporation into 810 Guidelines later; ✓ Consideration for additional use sites/strains is ongoing 	CQ#2: Issue #2
<ul style="list-style-type: none"> Expansion of virucidal claims to sanitizers (food and non-food) on porous and non-porous surfaces <p>Note: Not all aspects of this recommendation will be addressed by planned guidance, so this is also included in the long-term priorities/parking lot</p>	<ul style="list-style-type: none"> ✓ OPP is planning to post draft guidance by the end of FY21. 	CQ#2, Issue #2

Education

Recommendation	Deliverable	Recommendation Location
<ul style="list-style-type: none"> Continue to educate through every phase of the pandemic 	<ul style="list-style-type: none"> ✓ Provide ongoing updates to webpages and FAQs throughout the pandemic 	CQ#3, Issue #1
<ul style="list-style-type: none"> Provide information on when and how to use products based on sector for the pathogen of concern 	<ul style="list-style-type: none"> ✓ Included in List N as well as recent updates to Lists M (Avian influenza) and P (<i>Candida auris</i>) ✓ Develop: 1-pager on how to select/use products in multiple settings, etc. in multiple languages (Medium Priority implications) ✓ Potential for industry assistance on this effort for specific sectors 	CQ#3, Issue #1
<ul style="list-style-type: none"> Adjust product recommendations based on transmission routes/better clarification of products 	<ul style="list-style-type: none"> ✓ This has been partly addressed with the S18 pivot with more details when the pivot is finalized ✓ Additional information will be provided once surveys are gathered and analyzed ✓ Hyperlink to other agencies when necessary 	CQ#3, Issue #1

Collaboration

Recommendation	Deliverable	Recommendation Location
<ul style="list-style-type: none"> • Collaborate with other regulatory bodies and associations with specialized sector experience to develop appropriate sector-specific documents • Communicate with various regulatory agencies to find common avenues for consistent messaging and leveraging of resources 	<ul style="list-style-type: none"> ✓ Provide ongoing updates to webpages and FAQs throughout the pandemic ✓ Ongoing (Updates to variant explanation and infographics) ✓ One pager on how to select/use products in multiple settings, etc. (Medium Priority implications) ✓ *Webinars ongoing 	CQ#3, Issue #1
<ul style="list-style-type: none"> • Establish emergency procedures and product types (disinfectants) compatible with food safety 	<ul style="list-style-type: none"> ✓ Establish emergency procedures for FSMA/Some issues addressed additional clarification needed; accomplished through revising Food Code 	CQ#3, Issue #1

*Webinars (subset)

- 1) EPA IPM webinar, October 2020, "Addressing Disease Mitigation in Schools, Daycare Centers and Universities with Sanitizers and Disinfectants"
- 2) EPA IPM webinar, July 2021, "Pesticide Labels Demystified: Guidance on Understanding Pesticide Labels"
- 3) OAR webinar series "Healthy Indoor Environments in Schools: Plans, Practices and Principles for Maintaining Healthy Learning Environments"
- 4) CHPAC, Summer 2020, Children's Health Protection Advisory Committee
- 5) Numerous Pesticide Registration Education Program (PREP) trainings, 2020 and 2021
- 6) List N and disinfectant webinars to several EPA regions throughout 2021
- 7) Several ORD research webinars as well as the National Association of County and City Health Officials (NACCHO) 2021 conference.

Product Verification

Recommendation	Deliverable	Recommendation Location
<ul style="list-style-type: none">• Reassure products are suitable for use when used as directed	<ul style="list-style-type: none">✓ Confirm efficacy of registered products✓ For COVID-19 efficacy, some products (Section 18s and Section 3s) may be tested by MLB and/or ORD	CQ#3, Issue #1

Medium Priority: Overarching Topics



- **Process Efficiencies**

- **Surveys**

- **Improved Communication and Transparency**

- **Consistency**

- **Adverse Reporting**

Process Efficiencies

Recommendation	Deliverable	Recommendation Location
<ul style="list-style-type: none">• Integrate EVP approval process into efficacy reviews	✓ Include statement in efficacy review to alert PM to notify registrant of possible EVP claim and requirements in a future submission	CQ#1, Issue #2

Surveys

Recommendation	Deliverable	Recommendation Location
<ul style="list-style-type: none">• Conduct surveys at each phase of the pandemic or emergency to determine how to communicate and what have been done better	<ul style="list-style-type: none">✓ Compiling survey questions and results across some sectors✓ APIC is assisting with survey question development for use across multiple sectors.	CQ#3, Issue #1

Improved Communication and Transparency

Recommendation	Deliverable	Recommendation Location
<ul style="list-style-type: none">• Develop antimicrobial basics document for different audiences that best speak to those specific groups	<ul style="list-style-type: none">✓ Develop a basic document clearly defining antimicrobial products, use directions, classifications, contact times and other general information that could be tailored to different audiences✓ Can utilize survey results to identify gaps✓ Include in multiple languages✓ Potential for industry assistance.	CQ#3, Issue #1

Consistency

Recommendation	Deliverable	Recommendation Location
<ul style="list-style-type: none"> • Share insights on EPA policies and practices related to pandemic/emergency response to prevent divergence 	<ul style="list-style-type: none"> ✓ Host a meeting or put together a document that shares EPA’s insights on the pandemic. ✓ Numerous webinars* have been conducted across many sectors (listed below): 	<p>CQ#3, Issue #1</p>
<ul style="list-style-type: none"> • Assess regulations and identify where there are conflicting and synergistic messaging related to the use of disinfectants (across federal agencies) 	<ul style="list-style-type: none"> ✓ Develop a list of conflicting and synergistic regulations ✓ Potential for industry assistance. 	<p>CQ#3, Issue #1</p>

*Webinars (subset)

- 1) EPA IPM webinar, October 2020, “Addressing Disease Mitigation in Schools, Daycare Centers and Universities with Sanitizers and Disinfectants”
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Adverse Incident Reporting

Recommendation	Deliverable	Recommendation Location
• Develop a process for public to report adverse product reactions/incidents and misuses	✓ Develop FAQs with requisite hyperlinks to multiple resources	CQ#2, Issue #1

Recommendations Needing Process Development—Overarching Topics

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- Revision of EVP Guidance, CQ#1, Issues 1-2 and CQ#2, Issue 1
 - Icon/logo Development for EVP, CQ#1, Issue 2

- Expansion of EVP Guidance, CQ#2, Issue 1
- Adverse Incident Reporting, CQ#2, Issue 1

- Sustainability, CQ#2, Issue 1 (Potential for industry assistance)
- Communication/Education, CQ#3, Issue 1

- Industry Specific Practices, CQ#3, Issue 1 (Potential for industry assistance)
- Identification of Products for Specific Use Sites, CQ#3, Issue 1

Parking Lot (Long-Term Issues)— Overarching Topic

- Revision of EVP Guidance, CQ#1, Issue 2
- Revisions and/or expansion of PRN-98-10, CQ#2, Issue 2

- Suggestions for Section 18s, CQ#2, Issue 2
- EVP guidance, language and additional icon issues, CQ#2, Issue 2

- Efficacy Testing, CQ#2, Issue 2
- Process efficiencies, CQ#1, Issue 2

- Novel Technologies, CQ#2, Issue 2
- Expansion of virus claims/expanded use sites, CQ#2, Issue 2

- Expansion of viral hierarchy, CQ#2, Issue 2
- Regulatory Guidance for Future Pandemic/Emergencies, CQ#2, Issue 3

- Emergency Preparedness, CQ#2, Issue 4
- Communication/Collaboration, CQ#2, Issue 1 and CQ#4, Issue 1

- Industry Specific Testing—Airline, CQ#3, Issue 1
- Enforcement/Surveillance, CQ#4, Issue 1

Next Steps

- EPWG is set to sunset; all objectives have been met; resulting in an extensive list of recommendations
- A new workgroup under PPDC will be established with new name and charter
 - New name: EVP Implementation Workgroup
 - New charter: To provide the EPA support in the implementation of the recommendations provided by the former PPDC EPWG
- Request for new workgroup members to support implementation/operational phase
 - Interested?
 - Email: Tajah Blackburn (blackburn.tajah@epa.gov) AND Komal Jain (Komal_jain@americanchemistry.com)

Efforts Completed Prior to EPWG Closing

- Identify what can be developed by the new workgroup as thought starters for the EPA
 - Currently, reviewing and making recommendations to the EVP Guidance (responsive to Charge Question 1)
 - Trigger criteria
 - Definition of Emergency
 - Viral Product Eligibility Criteria
 - Assessing whether to develop survey questions to begin identifying sector gaps/needs (responsive to Charge Question 3)
 - Generated a list of potential questions to initiate surveys to respective sectors

Final Question to PPDC Membership

- Does the PPDC support the establishment of a new workgroup?
 - Charter: To provide the EPA support in the implementation of the recommendations provided by the former PPDC EPWG
 - Duration: June 2022 – December 2023 (TBD)



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Questions?